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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,447

04/27/2006

Ikurou Maruyama

2006_0649A

3430

513 7590 02/19/2008

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EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

02/19/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,447	Applicant(s) MARUYAMA ET AL.	
	Examiner Janet L. Epps-Ford	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-4 are presently pending for examination. Claims 1-3 were amended by Applicants.

Response to Arguments

Drawings

3. The objection to the drawings as set forth in the prior Office Action is withdrawn in response to Applicant's submission of new corrected drawings in compliance with 37 CFR 1.121(d) on 11/15/2007.

Claim Rejections - 35 USC § 102

4. The rejection of claims 1-2 under 35 U.S.C. 102(b) as being anticipated by Morgan et al. (WO 03/038107 A2, published May 08, 2003), is withdrawn in response to Applicant's amendment.

Claim Rejections - 35 USC § 112

5. The rejection of claims 3-4 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, is withdrawn in response to Applicant's amendment to the claims.

Claim Rejections - 35 USC § 103

6. Claims 1-4 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Morgan et al. in view of NCI-Antioxidant Cancer Prevention, for the reasons of record, and further in view of Buchter-Larsen et al. (US 6,914,175).

7. Applicant's arguments filed 11-15-2007 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that :

“[The administration of an antioxidant to a cancer patient is aimed at suppressing the side effects of an anticancer drug and it is well known that an antioxidant is not administered as an anticancer drug.” Furthermore, Applicant concluded that: "it is rare that an antioxidant functions as an antitumor agent, and the effect of the present invention that APP, known as an antioxidant, has an antitumor effect is not at all obvious.

Contrary to Applicant's assertions, Applicants have not provided any evidence or reference to support their assertion. See MPEP § 716.01(c)[R-2], which states: “[T]he arguments of counsel cannot take the place of evidence in the record.....attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements *regarding unexpected results*, commercial success, solution of a long-felt need, *inoperability of the prior art*, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.”

Moreover, contrary to Applicant's assertions, the prior art discloses the preparation of Ascopyrone P, and furthermore states that, “Ascopyrone P is known to function as a good antioxidant, and antimicrobial agent (Morgan et al., see page 1, 2nd paragraph).” Additionally, the art teaches that antioxidants may function to prevent cancer by the following mechanism: “[A]ntioxidants neutralize free radicals as the natural by-product of normal cell processes. Free radicals are molecules with

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incomplete electron shells which make them more chemically reactive than those with complete electron shells. Exposure to various environmental factors, including tobacco smoke and radiation, can also lead to free radical formation. In humans, the most common form of free radicals is oxygen. When an oxygen molecule (O₂) becomes electrically charged or "radicalized" it tries to steal electrons from other molecules, causing damage to the DNA and other molecules. Over time, such damage may become irreversible and lead to disease including cancer. Antioxidants are often described as "mopping up" free radicals, meaning they neutralize the electrical charge and prevent the free radical from taking electrons from other molecules."

Furthermore, Buchter-Larsen et al. teach a process for the preparation of an antioxidant in plant. Specifically, this reference teaches the preparation and use of 1,5-D-anhydrofructose (a precursor to ascopyrone) as a water soluble antioxidant (see col. 6, lines 1-12). Moreover, this reference provides another clear suggestion and motivation for using potent antioxidants as anticancer agents, see for example: col. 4, lines 5-10, which recite:

"[]The present invention is further advantageous in that it enables the levels of antioxidants in foodstuffs to be elevated. This may have beneficial health implications. In this regard, recent reports (e.g. Biotechnology Newswatch Apr. 21 1997 "Potent Antioxidants, as strong as those in fruit, found in coffee" by Marjorie Shaffer) suggest that antioxidants have a pharmaceutical benefit, for example in preventing or suppressing cancer formation."

Therefore, it would have been obvious to the ordinary skilled artisan at the time of the instant invention to combine the teachings of Morgan et al., the NCI Fact Sheet, and Buchter-Larsen et al. in the design of the instant invention. One of ordinary skill in the art would have been *motivated* to make this modification since the prior art clearly

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teaches that ascopyrone P and its precursor 1,5-D-anhydrofructose is a good antioxidant, and it was well known in the art that antioxidants help to prevent cancer, due to their ability to neutralize free radicals and protect cells from damage associated with the presence of excess electrical charge. Moreover, Buchter-Larsen et al. clearly teaches that these compounds have strong potential for preventing or suppressing cancer formation.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner
Art Unit 1633

JLE